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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,252	06/27/2001	Peter Styczynski	00216-552001 / H-245 (Kay	1872

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EXAMINER
BERMAN, ALYSIA

ART UNIT	PAPER NUMBER
1617	7

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/893,252	Applicant(s) STYCZYNSKI ET AL.	
	Examiner Alysia Berman	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *3-12,14-32 and 48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,13 and 33-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

1. Receipt is acknowledged of the amendment and sequence listing filed October 12, 2001. Claims 1-51 are pending. Claims 12 and 15 have been amended.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-48, drawn to a method of applying a composition, classified in class 514, subclass 2.

II. Claim 49, drawn to a method of applying a compound that reduces telomerase levels in hair follicles, classified in class 424, subclass 70.1.

III. Claim 50, drawn to a method of applying a compound that reduces telomerase mRNA expression in hair follicles, classified in class 424, subclass 70.1.

IV. Claim 51, drawn to a method of applying a compound that promotes the erosion of telomeric DNA in hair follicles, classified in class 424, subclass 70.1.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different

modes of operation. Group I requires the application of a composition and Group II requires the application of a compound.

4. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation. Group I requires the application of a composition and Group III requires the application of a compound.

5. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they have different modes of operation. Group I requires the application of a composition and Group IV requires the application of a compound.

6. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they require compounds that have different modes of operation. Invention II requires a compound that reduces telomerase levels and invention III requires a compound that reduces telomerase mRNA expression.

7. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they require compounds that have different modes of operation. Invention II requires a compound that reduces telomerase levels and invention IV requires a compound that promotes the erosion of telomeric DNA.

8. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they require compounds that have different modes of operation. Invention III requires a compound that reduces telomerase mRNA expression and invention IV requires a compound that promotes the erosion of telomeric DNA.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Groups III or IV, restriction for examination purposes as indicated is proper.

11. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group IV, restriction for examination purposes as indicated is proper.

12. This application contains claims directed to the following patentably distinct species of the claimed invention: an inhibitor of telomerase.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 33-46 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. During a telephone conversation with Robert Nabinger on January 28, 2002 a provisional election was made with traverse to prosecute the invention of Group I and the species ofloxacin, claims 1, 2 and 33-47. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3-12, 14-32 and 48-51 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claim 13 has been included with the claims drawn to the elected species because the compound of claim 13 is an optical isomer of the elected species. Absent evidence to the contrary, optical isomers are expected to have the same properties and are not patentably distinct.

14. The claims have been examined only as they relate to the elected invention and species.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Response to Amendment

16. The amendment filed October 12, 2001 is objected to because it does not include the statement "the sequence listing information recorded in computer readable form is

identical to the written (on paper or compact disc) sequence listing" and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d). A statement that the sequence listing information is identical is required.

17. The amendment filed October 12, 2001 contains data on compact disc(s). The compact disc is not identified in the transmittal letter and/or the transmittal letter does not list for each compact disc, the machine format, the operating system compatibility, a list of files contained on the compact disc including their names, sizes in bytes, and dates of creation, plus any other special information that is necessary to identify, maintain, and interpret the information on the compact disc as required by 37 CFR 1.52(e)(3). A statement listing the required information is required.

18. The amendment filed October 12, 2001 contains data on compact disc(s). The compact disc is not identified in the paper portion of the specification with a listing of all of the files contained on the disc. Applicant is required to amend the specification to identify each disc and the files contained on each disc including the file name, file size, and file creation date. See 37 CFR 1.52(e).

19. The amendment filed October 12, 2001 amends or adds a compact disc(s). See 37 CFR 1.77(b)(4) and 1.52(e)(5). Applicant is required to update or insert an incorporation-by-reference of the material on the compact disc(s) in the specification.

Specification

20. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

21. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

22. The disclosure is objected to because of the following informalities: Telomerase inhibitor II and telomerase inhibitor VII are identified as DNA sequences but are not also identified by sequence ID numbers.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

23. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

24. Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide a written description of androgen stimulated hair growth.

25. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

26. Claim 33, 37 and 40-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

27. Claim 33 is indefinite because it recites a concentration percent range but does not provide guidance as to how the concentration was measured. Is the concentration measured in weight, for example? Additionally, to what is the concentration relative, the total composition or particular components of the composition?

28. Claim 37 recites the limitation "said mammal". There is insufficient antecedent basis for this limitation in the claim.

29. Claims 40-43 recite the limitation "the human". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

30. Claims 1, 2, 13, 33-37, 39, 43, 45 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirota (US 4,923,862).

Hirota is directed to topical compositions containing ofloxacin (title) or its optical isomer (col. 1, lines 30-34). The optical isomer of ofloxacin is levofloxacin, which is claimed by Applicants in instant claim 13. At column 5, lines 15-26, Hirota describes topically applying a composition containing ofloxacin to an area of skin, specifically the abdomen (torso), that has been shaved. According to the examples at columns 1 and 2, the compositions contain from 0.1-5% ofloxacin. The dosage amount of ofloxacin in the composition of Hirota is from 0.5-50 mg/cm^2, which is equivalent to 500-50,000 mcg/cm^2. This dosage range overlaps the dosage range of instant claim 36.

The ability of a composition containing ofloxacin to reduce hair growth is inherent and is not given patentable weight over the prior art. A chemical composition and its properties are inseparable. The prior art teaches the same composition as instantly claimed and, therefore, inherently exhibits the same properties or effects when applied topically to an area of skin where hair grows. Therefore, the limitations of claims 34, 35 and 47 do not render the claims patentable over the prior art. The limitation of claim 45 is considered part of the preamble and is not given patentable weight over the prior art process.

The claims are directed to a process of applying a composition containing ofloxacin to skin. Hirota teaches topical application of a composition containing ofloxacin to the skin. The purpose of the process and the inherent properties of the composition or components of the composition do not render the claims patentable over the prior art.

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

32. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

33. Claims 1, 2, 13, 33-45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirota (US 4,923,862).

Hirota teaches all the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not teach application to the face, leg, arm, armpit, or application to an area of the skin of a woman with hirsutism.

Hirota teaches topical application of the compositions to the affected part of the skin (col. 6, lines 30-33).

It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the composition of Hirota to any affected area of the skin, including the face, leg, arm or armpit, expecting to obtain similar results.

34. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirota as applied to claims 1, 2, 13, 33-45 and 47 above, and further in view of Shander (US 4,720,489).

Hirota teaches all the limitations of the claims as stated in the 35 U.S.C. 102(b) and 103(a) rejections above. It does not teach an additional component that causes a reduction in hair growth. Hirota does teach topical application of ofloxacin after the application site has been shaved. One of ordinary skill in the art would understand that removal of hair and inhibiting re-growth at the application site would aid in absorption of ofloxacin into the skin.

Shander teaches topical application of a composition containing a compound that reduces hair growth (title, abstract and col. 1, lines 5-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add the hair growth reducing compound of Shander to the composition of Hirota in order to reduce hair growth at the application site to maintain absorption of ofloxacin into the skin.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-

4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

Alysia Berman
Patent Examiner
February 14, 2002

MINNA MOEZIE, J.D.
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